

46 87. (Amended) The method of claim ~~85~~ 44, comprising isolating KDR⁺early⁻ cells that do not express any late marker of the group consisting of

CD2, CD3, CD4, CD7, CD8, CD15, CD16, CD19, CD20, CD33, CD38, CD56, CD71, and glycophorin A

C5
C6
from other KDR⁺early⁻ cells.

48
49. 90. (Amended) The method of claim ~~89~~ 48, further comprising separating CD34⁻ cells that do not express a late marker (CD34⁻late⁻ cells) selected from the group consisting of CD2, CD3, CD4, CD7, CD8, CD15, CD16, CD19, CD20, CD33, CD38, CD56, CD71, and glycophorin A on their surface from other CD34⁻ cells, whereby the CD34⁻late⁻ cells are enriched for the HSCs.

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56. 97. (Amended) The method of claim ~~85~~ 48, wherein CD34⁻ CD38⁻ cells are isolated from a human hematopoietic tissue.

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59. 100. (Amended) The method of claim ~~99~~ 58, wherein the CD34⁻ cells do not express any late marker of the group consisting of CD2, CD3, CD4, CD7, CD8, CD15, CD16, CD19, CD20, CD33, CD38, CD56, CD71, and glycophorin A.

REMARKS

Claims 1-5, 7-11, 18-32, 51-53, 69, and 71-100 are pending after entry of this Amendment. Claims 25, 75, 77, 82, 86, 87, 90, 97, and 100 have been amended. Claims 1, 18, 51, 69, 80, and 83 are the only independent claims. The amendments and additions do not include new matter, as set forth in the ensuing section. No additional claim fee is believed to be due.

Support in the Specification

The amendment to claim 25 simply clarifies what was already recited in the claim in language that the Applicants hope the Examiner will find more acceptable.

Claim 75 has been amended simply to correct a grammatical error.

Claim 77 has been amended simply to incorporate the recitations of claim 25.

The recitation added to claim 97 that the CD34⁺ CD38⁻ cells are isolated from a human hematopoietic tissue is supported in the specification, for example at page 13, lines 21-27.

Claims 82, 86, 87, 90, and 100 have been amended simply to delete CD45 from the list of late markers that appears in each of these claims. In each instance, the Applicants are simply claiming less than the entirety of the subject matter that was originally disclosed.

For the reasons set forth above, the Applicants respectfully contend that the amendments and additions made herein do not include new matter.

Priority Claim

The Examiner is requested to acknowledge the Applicants' claim pursuant to 35 U.S.C. § 119(e) to priority to U.S. provisional application no. 60/087,153, filed 29 May 1998 (the appropriate box - item 14 - was not checked on the Office Action Summary sheet).

Rejection of Claims Pursuant to 35 U.S.C. § 112, First Paragraph

Claims 9, 31, 32, and 96 stand rejected pursuant to 35 U.S.C. § 112, first paragraph. In the Examiner's view, the invention recited in these claims is not enabled because the Applicants did not sufficiently demonstrate that the monoclonal antibody designated 260.4 was publicly available at the time the invention was made. The Applicants respectfully suggest that the Examiner misunderstands when a biological material must be available to the public for enablement purposes, and that it is immaterial whether the material was publicly available when the invention was made. The Examiner is referred to 37 C.F.R. § 1.804(a) and M.P.E.P. § 2406. For enablement purposes, biological material needed to practice a claimed invention must be made available to the public not later than the issue date of the corresponding patent application.

In the Amendment filed by the Applicants on 2 July 2001 (believed to be Paper No. 11), the Applicants established that monoclonal antibody 260.4 is presently available from Sigma Chemical Company as product number V3003. Thus, the Applicants respectfully contend that this monoclonal antibody is available to the public from a source not owned or controlled by the Applicants, and that the enablement requirement of 35 U.S.C. § 112, first paragraph, is satisfied.

The Examiner is respectfully requested to reconsider and withdraw the rejection of claims 9, 31, 32, and 96 pursuant to 35 U.S.C. § 112, first paragraph.

Claims 97 and 98 stand rejected pursuant to 35 U.S.C. § 112, first paragraph. In the Examiner's view, these claims would be supported if they recited that the CD34⁺ CD38⁻ cells are isolated from human hematopoietic tissue. These claims have been amended to include this recitation, and the Examiner's rejection is believed to be overcome.

Withdrawal of the rejection of claims 97 and 98 pursuant to 35 U.S.C. § 112, first paragraph, is respectfully requested.

Rejection of Claims Pursuant to 35 U.S.C. 112, Second Paragraph

The Examiner rejects claim 25 pursuant to 35 U.S.C. § 112, second paragraph. In the Examiner's view, the meaning of the claim was not clear. The Applicants have amended claim 25 to remove any ambiguity as to the meaning of the claim. The Applicants believe that the claim can only be interpreted to mean that the recited antibody can be either an antibody specific for an early marker or an antibody specific for a late marker. The Examiner is requested to withdraw the rejection of claim 25 pursuant to 35 U.S.C. § 112, second paragraph, in view of this clarification.

The Examiner rejects claims 83-100 pursuant to 35 U.S.C. § 112, second paragraph. In the Examiner's view, the term "first early marker" is not clear. The Applicants respectfully disagree. The term "early marker" is used throughout the specification (see, e.g., page 21, lines 11-13, and page 22, lines 11-23) and in many of the allowed claims, such as claims 24, 26, 76, and 79. The word "first" is merely an arbitrary designation used to

distinguish this early marker from another early marker recited in other claims (e.g., a "second" early marker recited in claim 84). The Applicants respectfully contend that skilled artisans would have no difficulty interpreting the terms "first early marker" and "second early marker" to mean simply two different early markers.

In view of the foregoing clarification, the Applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 83-100 pursuant to 35 U.S.C. § 112, second paragraph

Summary

The Applicants submit that each rejection of the claims has been either overcome or is now inapplicable, and that each of claims 1-5, 7-11, 18-32, 51-53, 69, and 71-100 is now in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

In the event the Examiner is not inclined to allow one or more claims, the Applicants request that the Examiner telephone the Applicants' undersigned representative so that this application can be moved to allowance as expeditiously as possible.

Respectfully submitted,

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(Date)

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Enclosures Marked-Up Copy of Amended Claims
Clean Copy of Claims, As Amended